(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 January 2005 (27.01.2005)

PCT

(10) International Publication Number
WO 2005/007037 A1

(51) International Patent Classification[7]: A61F 2/24

(21) International Application Number:
PCT/US2004/021886

(22) International Filing Date: 9 July 2004 (09.07.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/617,610 11 July 2003 (11.07.2003) US
10/617,609 11 July 2003 (11.07.2003) US

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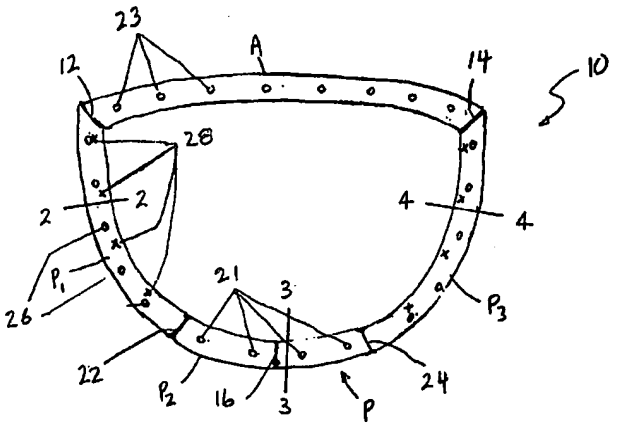
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SELECTIVE ANNULOPLASTY FOR ATRIO-VENTRICULAR HEART VALVE REGURGITATION AND DEVICES THEREFOR



(57) Abstract: An annuloplasty ring (10) includes an anterior portion (A), and a posterior portion (P) which defines a central portion (P2) and two lateral portions (P1, P3). The ring (10) is adapted for optional removal of the anterior (A) and/or the central posterior portion (P2). Removal of the central posterior portion (P2) reduces the gradient across the ring (10) providing enhanced valve performance. Removal of the anterior portion (A) preserves normal annular movement. The lateral posterior portions (P1, P3) are stiffer than the construction at the anterior (A) and central posterior portions (P2). If the ring (10) is used with the central posterior portion (P2) intact, the gradient is also reduced. The ring (10) includes indicia of multiple sets of suture markings (21,23), each set identifying a plurality of suture locations about the perimeter of the ring (10) that are adapted to cinch the annulus a predetermined amount about the ring. A single ring (10) may be used to cinch the annulus in accord with relatively different degrees of desired valve area reduction. According to another embodiment, cinching is accomplished via shape memory alloy implants which are implanted internal or external of the heart and may be deployed with a catheter.

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Selective Annuloplasty for Atrio-Ventricular Heart Valve Regurgitation

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates broadly to implantable prostheses. More particularly, this invention relates to annuloplasty rings specifically adapted for the valves of the heart.

2. State of the Art

Mitral regurgitation is a "leaking" of the mitral valve which connects the left atrium and the left ventricle of the heart. When the left ventricle contracts to eject blood to the rest of the body, the mitral valve closes to prevent blood from passing in the wrong direction; i.e., into the left atrium. When the mitral valve fails to close properly and mitral regurgitation (MR) develops. If the MR is severe, mitral valve repair or replacement is needed to preserve the function of the left ventricle and to prevent congestive heart failure from developing. Mitral valve repair is often done to eliminate MR and prevent the necessity of mitral valve replacement.

During mitral valve repair, a portion of the redundant valve tissue is resected and the valve leaflets are reshaped to eliminate MR. In degenerative disease of the mitral valve leaflets, the annulus about the leaflets typically increases by approximately one hundred to two hundred percent. In such case, an annuloplasty ring is provided at the annulus and the annulus is sewn to the ring to create a purse string effect around the base of the valve which helps the leaflets meet when the valve closes. This also restores the anatomical size and shape of the valve and supports the repaired mitral valve to prevent recurrent dilatation. Due to the excess leaflet tissue caused by degenerative disease, any size mismatching of the annuloplasty ring and the mitral annulus is of little consequence.

However, in heart failure, the leaflets are not enlarged. Thus, choosing the appropriate size for an annuloplasty ring is critical to avoid the occurrence of MR from continuing dilatation of the heart.

Each of the anterior and posterior leaflets of the annulus is divided by nomenclature into thirds. The anterior leaflet has a leftmost portion A_1, a central portion A_2, and a rightmost portion A_3. Similarly, the posterior anterior leaflet has a leftmost portion P_1, a central portion P_2, and a rightmost portion P_3. early leakage of the mitral valve in heart failure starts at two specific locations, namely P_1 and P_3. However, P_2 is the portion directly in the path of blood from the left atrium to the ventricle.

It has been noted by the present inventor that prior art mitral annuloplasty rings effect an undesirable gradient across the mitral valve which may cause a backflow of blood into the lungs. Prior art mitral annuloplasty rings remodel the annulus by providing a 3:4 ratio between the anteroposterior and transverse diameters of a normal mitral valve for what is generally considered optimal hemodynamic performance. In addition, the outer cross-sectional diameter of a state of the art ring is relatively uniform about its circumference.

Annuloplasty rings are typically made of flexible polymers and generally are available in ring-shaped (annular) or C-shaped configurations. The C-shaped designs include a posterior portion (including substantially transverse lateral portions and a central portion therebetween), but no anterior portion, which operates to effect a reduced gradient (but does not eliminate the gradient). In addition, some annuloplasty rings, e.g., the Sulzer Carbomedics AnnuloFlex™ ring and the St. Jude Medical Tailor™ ring, have a ring-shaped configuration that is adapted to be converted into a C-shaped configuration by removal of the anterior portion of the ring. Annuloplasty rings generally also include commissure guides (or trigone markings) by which to reference a ring relative to the left and right valve leaflet commissures (or left and right fibrous trigones) and the posterior midline of the valve annulus to facilitate implantation.

Annuloplasty rings are also available in a variety of sizes permitting selection of a ring which most appropriately corresponds to the intended size of the post-operative annulus. However, this requires that a medical care facility stock each of the variety of sizes, thereby complicating inventory control. Each size of ring includes thereon, or has associated therewith a guide which includes, markings indicating spaced-apart locations for a set of suture ties so that the ring can be coupled to the mitral valve annulus.

The problems noted above are not limited to the mitral valve, but are also relevant to the tricuspid valve (with references to the appropriate nomenclature).

SUMMARY OF THE INVENTION

It is therefore an object of the invention to provide an annuloplasty ring that can produce multiple degrees of valve area reduction by having spaced-apart markings producing different degrees of reduction of the annulus, thereby obviating the need to stock as many sizes of rings as in the prior art.

It is another object of the invention to provide an annuloplasty ring which provides desirable hemodynamic performance.

It is a further object of the invention to provide an annuloplasty ring which reduces a gradient across the valve to physiological levels.

It is also an object of the invention to provide an annuloplasty ring which can be used in a ring-shaped configuration, a C-shaped configuration, and other configurations most suitable to treat valve regurgitation.

In accord with these objects, which will be discussed in detail below, an annular annuloplasty ring includes an anterior portion and a posterior portion having central and substantially transverse lateral portions. Alternatively, the ring may be C-shaped and formed without the entirety of, or a portion of, the anterior portion.

Regardless of whether the ring is completely annular or C-shaped, according to a first preferred aspect of the invention, the ring includes a posterior portion defining a central portion and two lateral portions. The ring is adapted in construction for stabilization and non-reduction of the central posterior portion, while significant reduction of lateral portions is facilitated. It has been determined by the inventor that, in many cases, reduction of the central posterior portion of the ring results in an increased gradient. Therefore, the ring of the invention does not reduce, but only stabilizes the central portion of posterior leaflet, and

consequently decreases the gradient across the valve relative to prior art rings which cinch a central posterior portion of the valve annulus.

According to a second preferred aspect of the invention, the construction of the ring at the lateral posterior portion is different than the construction at the central posterior portion (i.e., the portion adapted to optionally be removed). The lateral posterior portions are substantially stiffer than the central posterior portion. A softer central posterior portion minimizes a gradient where the central posterior portion remains integral with the ring, while the lateral posterior portions contribute strength and competence of the valve during closure of the leaflets. One preferred manner of effecting stiffer lateral posterior portions is to construct the sides as relatively flatter than a more tubular central portion.

From the foregoing, it is appreciated that the annuloplasty ring of the invention is hemodynamically optimized to reduce a gradient thereacross, and improve competence of the valve leaflets by selectively reducing the lateral posterior portions.

According to a third preferred aspect of the invention, the ring includes indicia of multiple sets of suture markings, each set identifying a plurality of suture locations about the perimeter of the ring which are adapted to cinch the annulus by a predetermined amount about the ring. Thus, a single ring may be used to cinch the annulus in accord with relatively different degrees of desired valve area reduction. This is in contrast to the prior art, where multiple rings of different dimensions are required for the same effect. Thus, each ring of the invention corresponds to multiple rings of different sizes and reduction capabilities of the prior art.

According to another embodiment of the invention, an annuloplasty ring is not required to effect stabilization of P_2 and cinching of P_1 and P_3. Rather, such cinching is accomplished via shape memory alloy (SMA) implants which are implanted internally or externally of the heart. Such implants may be deployed with a catheter.

All the above concepts with respect to the mitral valve can be applied to the tricuspid valve.

Additional objects and advantages of the invention will become apparent to those skilled in the art upon reference to the detailed description taken in conjunction with the provided figures.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a plan view of a mitral annuloplasty ring according to the invention;

Fig. 2 is a cross-section across line 2-2 in Fig. 1;

Fig. 3 is a cross-section across line 3-3 in Fig. 1;

Fig. 4 is a cross-section across line 4-4 in Fig. 1;

Fig. 5 illustrates the mitral annuloplasty ring of the invention shown implanted, where both the anterior and posterior portions of the ring are used;

Fig. 6 illustrates the mitral annuloplasty ring of the invention shown implanted, where the anterior portion of the ring is removed;

Fig. 7 illustrates the mitral annuloplasty ring of the invention shown implanted, where both the anterior portion and central posterior portions of the ring are removed, leaving only the lateral posterior portions of the ring implanted at the valve;

Fig. 8 is a second embodiment of a mitral valve annuloplasty ring according to the invention;

Fig. 9 is an embodiment of an instrument which includes suture guides in accord with the invention;

Fig. 10 illustrates SMA implants shown implanted internally along P_1 and P_3;

Fig. 11 is a view similar to Fig. 10 with a link shown between the SMA implants;

Fig. 12 illustrates SMA implants shown implanted externally along P_1 and P_3;

Fig. 13 is a view similar to Fig. 12 with a link shown between the SMA implants;

Fig. 14 illustrates embodiments of SMA implants implanted internally at the P_1/P_2 and P_2/P_3 junctions;

Fig. 15 illustrates other embodiments of SMA implants implanted internally at the P_1/P_2 and P_2/P_3 junctions;

Fig. 16 illustrates embodiments of SMA implants implanted externally at the P_1/P_2 and P_2/P_3 junctions;

Fig. 17 illustrates other embodiments of SMA implants implanted externally at the P_1/P_2 and P_2/P_3 junctions;

Fig. 18 illustrates embodiments of SMA implants implanted internally at the P_1/P_2 and P_2/P_3 junctions, and an externally implanted implant intended to stabilize the P_2 leaflet;

Fig. 19 illustrates pre-activated and post-activated configurations of SMA implants implanted internally at the P_1/P_2 and P_2/P_3 junctions;

Fig. 20 illustrates a pre-activated arced SMA implant deployed across the anterior/posterior leaflet valve junction of a tricuspid valve;

Fig. 21 illustrates the implant of Fig. 20 in a post-activated configuration;

Fig. 22 illustrates a pre-activated straight SMA implant deployed across the anterior/posterior leaflet valve junction of a tricuspid valve;

Fig. 23 illustrates the implant of Fig. 22 in a post-activated configuration;

Fig. 24 is a schematic of a deployment catheter for an SMA implant shown with a straight SMA implant;

Fig. 25 is a distal end view of a catheter of Fig. 24; and

Fig. 26 is a view similar to Fig. 25 showing an arced SMA implant at the distal end of the deployment catheter.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning now to Fig. 1, a mitral annuloplasty ring 10 is shown. The ring 10 includes a shallowly curved anterior portion A, and a steeper curved posterior portion P. The ring is preferably provided with trigone guides 12, 14 (or alternatively commissure guides) and optionally a posterior midline guide 16 which together facilitate alignment of the ring relative to anatomical landmarks of the mitral valve. Referring to Figs. 2 through 4, the ring 10 is preferably constructed of an inner structural constituent 18, e.g., resilient polytetrafluoroethylene (PTFE), which is surrounded by a fabric outer layer 20 through which suture needles and suture can be passed to secure the ring at the valve annulus. Other materials known in the art can also be used in the alternative or in combination with the above described materials.

According to a first preferred aspect of the invention, the posterior portion P includes a central portion P_2 and substantially transverse lateral portions P_1 and P_3 on either side of the central portion. The central posterior portion P_2 is preferably approximately 20 to 25 mm in length. The ring 10 is preferably adapted in construction for optional removal of the central posterior section P_2, preferably after implantation of the ring at the valve. (See Fig. 7.) That is, the ring 10 at the junction of P_1 and P_2 and junction of P_2 and P_3 preferably includes indicia 22, 24 indicating where a blade may be used to cut the ring and/or is provided with a weakened section (e.g., reduced diameter), or even a discontinuity, of the structural constituent 18 at the indicated locations 22, 24 to facilitate cutting and removal of the central posterior portion P_2. If removal of the central portion P_2 is performed, it is preferably performed after suturing the lateral posterior portions P_1 and P_3 at the valve annulus. It has been determined by the inventor that, in many cases, the central posterior portion P_2 of the

ring 10 is not required to abate MR or support the annulus and may, in fact, contribute to an excessive gradient across the ring 10. By eliminating the central posterior portion P_2, the gradient is reduced relative to prior art to thereby provide superior results.

It has also been determined by the inventor that, in many cases, reduction of the P_2 of the valve annulus contributes to an excessive gradient across the ring 10. The P_2 portion of the ring 10 includes suture markings 21 (represented by circles) which are spaced so as to effect no annular reduction if the P_2 portion of the ring is kept intact and coupled to the valve. By not reducing the central posterior portion P_2, the gradient is reduced relative to prior art to thereby provide superior results. In addition, similarly spaced-apart markings 23 (also represented by circles) between indicia 12 and 14 (Fig. 1) of the anterior leaflet are provided so as to not effect reduction of the anterior annulus.

Referring to Figs. 2 through 4, and according to a second preferred aspect of the invention, the construction of the ring at the lateral posterior portions P_1 and P_3 is different than the construction at the central posterior portion P_2. The lateral posterior portions P_1, P_3 are slightly stiffer than the central posterior portion P_2. One preferred manner of effecting stiffer lateral portions P_1 and P_3 is to construct the sides relatively flatter, and the central posterior portion P_2 more cylindrical. That is, the lateral posterior portions P_1 and P_3 preferably have a smaller dimension in the direction of blood flow and a relative greater dimension transverse to the direction of blood flow. The more flexible central posterior portion P_2 minimizes a gradient where the central posterior portion remains integral with the ring after implantation. In addition, the lateral posterior portions P_1, P_3 contribute strength, but do not significantly affect the gradient. The similarly structured more flexible anterior portion allows preservation of normal annular movement during the cardiac cycle.

From the foregoing, it is appreciated that the mitral annuloplasty ring of the invention is hemodynamically optimized to reduce a gradient thereacross.

Referring back to Fig. 1, according to a third preferred aspect of the invention, the ring 10 includes multiple circumferential sets 26, 28 of indicia (where only a subset of each set of indicia is identified by the reference numerals) for suture placement. Fig. 1 distinguishes the sets of indicia based upon a discrete shape (e.g., circles 26 and cruciforms 28) for ease of

distinction in the black and white drawing. However, distinctions based upon discretely colored markings (e.g., colored sutures extending circumferentially about the ring) or other visual indicators may be preferred. Each marking within a set 26, 28 is preferably spaced apart from another marking of the same set by a predetermined distance (e.g., 2.5 mm or 3.0 mm or similar increments). Each set 26, 28 of indicia thusly corresponds to a predetermined amount of cinching about the ring 10. The physician selects one of the plurality of sets of markings according to the degree by which the physician assesses that the valve annulus should be cinched. Thus, a single ring may be used to cinch the annulus in accord with relatively different degrees of desired valve area reduction. In contrast, the prior art would require different rings each optimized for a different size of reduction.

Alternatively, for example, the indicia corresponding to multiple sets of suture locations sizes may be provided to instrumentation, such as a ring holder to thereby guide the surgeon to the same effect. Referring to Fig. 9, instrument 50 includes a handle 52 having a manual gripping element 54 at one end and a ring holder 56 removably coupled at its other end. Such ring holders are well known in the art. In accord with the invention, the ring holder 56 is coupled to a ring 10, e.g., with sutures (not shown), and includes multiple sets of suture guides 58 (circles), 60 (cruciforms) along portions of the holder 10 which correspond to the P_1 and P_3 portions of the ring 10. The portions of the holder 10 which correspond to the P_3 and anterior portions of the ring 10 are each preferably provided with a single set of suture guides 62 (along P_3) and 64 (along the anterior portion).

An annuloplasty ring 10 according to the invention may be implanted in any of three configurations at the mitral valve. Referring to Fig. 5, in accord with the a first method of implantation, the valve annulus 40 is sutured to both the anterior and posterior portions A and P of the ring 10. Thus, the ring 10 is circumferentially continuous (with the anterior portion A intact) in its implanted state. Referring to Fig. 6, in a second method of implantation, the valve annulus 40 is sutured to the posterior portions P_1, P_2 and P_3 of the ring 10, and the anterior portion of the ring is removed from the implant, e.g., by cutting. While the central posterior portion P_2 remains intact, the structural design of this portion operates to limit the gradient across the anterior portion of the valve. Referring to Fig. 7, in a third method of implantation, the valve annulus is sutured to the lateral posterior portions P_1 and P_3 of the ring, but not the central posterior portion P_2 or the anterior portion A. The central posterior

portion P_2 and anterior portion A are then removed from the ring after the valve annulus is secured to the lateral posterior portions P_1 and P_3. As the ring is structurally stiffer along the lateral posterior portions, the annulus is nevertheless stably supported. Moreover, removal of the central posterior portion P_2 greatly reduces the gradient across the valve and provides a superior result relative to prior art annuloplasty rings. Thus, the invention includes a method whereby the lateral posterior portions of an annulus are supported by an implant, but the anterior and central posterior portion of the annulus are unsupported by an implant so as to reduce a gradient across the mitral valve.

Turning now to Fig. 8, another embodiment of an annuloplasty ring according the invention is shown. The ring 110 is C-shaped and formed without a significant portion of the anterior portion A or even the entirety thereof. Preferably, all other features of ring 10, e.g., a construction permitting removal of central portion P_2 and a plurality of sutures sets, are incorporated into ring 110. The ring may be implanted in accord with the methods described with respect to Figs. 6 and 7.

According to embodiments of the invention which follow, an annuloplasty ring is not required to effect stabilization of P_2 and cinching of P_1 and P_3. Rather, such cinching is accomplished via shape memory alloy (SMA) implants which are implanted internal or external of the heart. Referring to Figs. 24 and 25, the implants 180 are preferably positioned within the distal end of a steerable catheter 182, either in a straight configuration (Fig. 25) or slightly arced shape (implant 186 of Fig. 26). The catheter 182 is maneuvered through an anatomical approach such that the implant 180 is positioned at the appropriate valve annulus, and actuation and activation mechanisms of the catheter instrument 184 are operated to release and activate the implant 180. Each implant 180 is preferably no more than 20 mm in length, and most preferably does not exceed 15 mm in length, and multiple implants may be implanted as described as follows to abate leaks of the valve.

The metallurgy and manufacture of SMAs, made for example from nickel-titanium alloy, and devices therefrom is well known in the art. In brief, the SMA implants are trained such that when a predetermined amount of energy is applied to the SMA implants, the device changes shape in a predefined manner. Such energy may be the natural heat of body temperature or more preferably is provided by external application such as with the surgical

instrument (i.e., the deployment catheter 182) via electrical current, magnetism, heat conduction, RF energy, etc. Lead 186 permits such external application (Fig. 25). A portion or portions of any of the SMA implants is preferably, though optionally, covered with a plastic or fabric (e.g., PTFE fabric) which increases the surface area of the portion of the implant and functions as a boundary which will not tear through the annulus and which has a desired amount of 'give' to prevent injury to the tissue. In a surgically stabilized implant, such shape change of the SMA implants operates to cinch the posterior leaflet or other specific locations of implantations at the valve, as described below. It is noted that the following described figures are provided to illustrate the location of implantation of various implants and the shape of the implanted implants, but are not necessarily true representations of the respective valve anatomy before and after cinching.

Referring to Fig. 10, a first SMA implant 202 is implanted internally (within the heart muscle, e.g., inside the annulus 210) along the P_1 leaflet and preferably also slightly overlapping the P_1/P_2 junction such that when the implant is activated to cause its shape to change, the implant 202 causes cinching and reduction of P_1 and its junction with P_2. A second SMA implant 204 is implanted internally along the P_3 leaflet and preferably slightly overlapping the P_2/P_3 junction such that when activated to cause its shape to change, the implant 204 causes cinching and reduction of P_3 and its junction with P_2. The commissures 212 may also be included in the cinched areas.

Referring to Fig. 11, implants 202 and 204 may be connected by a link 206 which does not change shape so as to cause cinching upon application of the predetermined amount of energy, but rather stabilizes implants 202 and 204 relative to each other by creation of a continuous implant. That is, link 206 is analogous to the P_2 portion of the ring 10 in Fig. 1. Thus, link 206, if also manufactured of the same SMA as 202 and 204, is preferably trained to maintain its shape even upon application of the predetermined amount of energy. Alternatively, link 206 may be in the form of a wire, chain, or other suitable structure. The link may include structure such as barbs or hooks for stabilization to tissue. The link 206 facilitates implantation for the surgeon while stabilizing P_2 and not resulting in an increased gradient across the valve.

Turning now to Fig. 12, SMA implants 202, 204 can also be implanted externally of the heart (i.e., outside the valve and heart chamber), e.g., within the coronary sinus 214, and still be designed so as to effect the required cinching. Implant 202 is positioned within coronary sinus 214 along the P_1 leaflet and preferably also slightly overlapping the P_1/P_2 junction such that when energy is applied to activate the implant to change its shape, the implant 202 causes cinching and reduction of P_1 and its junction with P_2. Implant 204 is implanted in the coronary sinus along the P_3 leaflet and preferably slightly overlapping the P_2/P_3 junction such that when the implant is activated, the implant 204 causes cinching and reduction of P_3 and its junction with P_2. While the implants 202, 204 route external the heart, the anterior ends 218, 220 thereof are preferably adapted to be bent to pierce the annulus 214 near the commissures 212 or lateral portions 222a, 222b, of the anterior leaflet A in order to effect cinching of the annulus along preferably the entire length of P_1 and P_3. Referring to Fig. 13, the externally implanted implants 202, 204 can also be coupled with a link 206.

Turning now to Figs. 14 through 20, other SMA implants and methods of cinching just the P_1/P_2 and P_2/P_3 junctions, without cinching substantial portions of length the P_1, P_2 or P_3 portions of the posterior leaflet are shown. This is often desirable, as most leaking of the valve occurs at the junctions. Referring particularly to Fig. 14, the system includes two devices 302, 304 each comprising tab-like ends 306 which can reside internally or externally the heart, and an SMA portion 308 which reshapes upon activation to cause cinching of the associated junction. Referring to Fig. 15, the system includes two devices 402, 404 each comprising a bar like element 406 spanning the associated junction. The elements preferably do not extend through the annulus, but rather extend across the junction. The ends of the elements are provided with barbs or hooks 408 or other tissue attachment structure. Upon activation of the devices 402, 404, cinching is caused about the associated junction. Another method of the system includes bars, staples, or other devices which are pierced through the heart to constrict the annulus from under the surface of the leaflets.

Referring to Fig. 16, the system includes two straight, arced, squared 'U'- or C-shaped staple devices 502, 504 which are implanted externally from the coronary sinus 214, but pierce into the annulus 210 under or over the leaflets at the posterior junctions. Referring to Fig. 17, the staple devices 502, 504 are then shaped, e.g., into a circle, oval, or triangle, to cause the junctions to be cinched. The staple devices 502, 504 are preferably made of SMA

which can be activated by application of energy to enter the desired shape. Thus, as described, this embodiment includes external deployment with internal anchoring.

Turning to Fig. 18, various other implants are shown. Implant 602, at the P_1/P_2 junction, shown in an active 'cinching' form is in the shape of a spiral. Implant 604, at the P_2/P_3 junction, shown in an active 'cinching' form is C-shaped with spirals at each end. Implant 606 is shown stabilizing, but not cinching, the P_2 portion of the annulus.

Referring to Fig. 19, implant 702a is shown in a pre-activated form suitable for catheter deployment into the annulus. The implant 702a has barbed ends 704. Implant 702b is the same shape implant shown in a post-activated form in which the implant takes the general form of a 'V' with curved, curled or spiraled ends which engage the tissue of the annulus and pull the tissue to cinch the annulus upon activation.

From all of the above, it is appreciated that the SMA implants may take numerous shapes. In summary of the described shapes, the pre-activated and post-activated configurations are one of the following:

i) pre-activated shape of straight or arced and post-activated shape of a 'U' or a 'C';

ii) pre-activated shape of straight or arced and post-activated shape of a 'C' with curled ends;

iii) pre-activated shape generally of a 'C' and a post-activated shape of a 'C' with curled ends;

iv) pre-activated shape of a 'C' and post-activated shape of a spiral; and

v) pre-activated shape of straight or arced and post-activated shape of a 'V' with curled ends.

Other suitable shapes are within the scope of the invention.

While all the above described embodiments have been described with respect to the mitral valve, the described annuloplasty ring can be adapted for the tricuspid valve, and the SMA implants can be used to cinch the junctions of the leaflets in the tricuspid valve, as well. The tricuspid valve has three leaflets and thus three leaflet junctions. The leaflets are termed septal, anterior and posterior. The septal leaflet adjoins the septum between the left and right ventricles and generally cannot be cinched as it is relatively stiff and immobile along its

length. The anterior leaflet is located in the superior right portion of the valve. Its junction with the septal leaflet can be cinched in a manner similar to that described above. The posterior leaflet is located in the inferior and right portion of the valve. Its junction with the septal leaflet may be cinched as well as its junction with the anterior leaflet. In fact, the anterior-posterior junction is the most prevalent location for leakage.

Regarding an annuloplasty ring, the removable anterior portion of the ring in the mitral embodiment is comparable to the septal portion of a tricuspid embodiment and the P_1/P_2 and P_2/P_3 junctions correspond to the anterior-septal, anterior-posterior and posterior-septal junctions. The indicia on the ring is modified accordingly to provide the appropriate cinching.

Also in the manner described above, the SMA implants may be used to internally or externally cinch the identified junctions on the tricuspid valve, though for an external approach anatomy similar to the coronary sinus is not so well defined about the tricuspid valve so as to facilitate external cinching. However, the existing cardiac veins would permit external deployment provided the catheter and implants were sufficiently small.

By way of one example, referring to Fig. 20 a tricuspid valve 800 is shown with a pre-activated implant 802a deployed across the anterior-posterior 'A/P' junction. Referring to Fig. 21, upon activation, the implant 802b changes shape to take the form generally of a 'V' with curled ends, causing a loop 804 (exaggerated for clarity) of the junction to be excluded from the operational portion of the annulus.

By way of another example, referring to Fig. 22, a tricuspid valve is shown with a pre-activated implant 902a deployed across the anterior-posterior 'A/P' junction. Referring to Fig. 23, in a post-activated configuration, the implant 902b has caused the junction to be cinched inward at A/P.

In accord with the methods of the invention, the implants for cinching may be deployed to the mitral valve via one or more catheters which are fed up through the femoral vein to the mitral valve. Alternatively or in addition, the catheter may be entered at the jugular vein into the right side of the heart, across the inter-atrial septum and into the left side of the heart to the mitral valve. In such an approach, catheter length is greatly reduced and

deployment torque and accuracy is greatly increased. For the tricuspid valve, the catheter can be fed under radiographic guidance in a conventional approach from the femoral vein to the heart. Alternatively or in addition, the catheter can be entered at the jugular vein in a direct approach straight into the right side of the heart.

Thus, there has been described methods and devices for selectively cinching portions of the annulus and the junctions of a heart valve such that the annulus of the valve is reduced at selective locations and not at other locations around the annulus of the valve. Such cinching reduces leaks through the valves. Moreover, certain devices described for accomplishing the cinching, short implants which do not require a length sufficient to extend around an entire leaflet, permit easier and faster deployment and more effective results.

Furthermore, while ring-like devices (generally for open surgery) and SMA devices (preferably for thoracoscopic or catheter-based surgery) are preferred for their facility in deployment, it is appreciated that other devices may also permit selectively cinching of the junctions of the heart valves and portions of the leaflets of the annulus of the mitral and tricuspid valves. For purposes herein, 'cinching' is defined as constricting.

While particular embodiments of the invention have been described, it is not intended that the invention be limited thereto, as it is intended that the invention be as broad in scope as the art will allow and that the specification be read likewise. It will therefore be appreciated by those skilled in the art that yet other modifications could be made to the provided invention without deviating from its scope as claimed.

What is claimed is:

1. A mitral annuloplasty device, comprising:

a ring-shaped structural component sized for mitral valve annuloplasty, said structural component having a relatively shallowly curved portion and a relatively steeper curved C-shaped portion including a central portion and first and second lateral portions,

wherein said C-shaped portion includes demarcations between said first lateral portion and said central portion and between said central portion and said second lateral portion facilitating removal of said central portion from between said first and second lateral portions.

2. An annuloplasty device according to claim 1, wherein:

said relatively shallowly curved portion is an anterior portion, and said C-shaped portion is a posterior portion.

3. An annuloplasty device according to claim 1, wherein:

said demarcations are structural.

4. An annuloplasty device according to claim 3, further comprising:

visual indicia coincident with said structural demarcations.

5. An annuloplasty device according to claim 4, wherein:

said structural component is provided with a relatively softer outer layer, and said visual indicia is provided on said outer layer.

6. An annuloplasty device according to claim 4, wherein:

said first and second lateral portions each include one of a trigone marking and a commissure marking.

7. An annuloplasty device according to claim 1, wherein:

said lateral portions are oriented substantially transverse to said central portion.

8. An annuloplasty device according to claim 1, wherein:

said central and first and second lateral portions define a plane, and said first and second lateral portions are relatively stiffer than said central portion in a direction transverse to said plane.

9. An annuloplasty device according to claim 1, wherein:

said central portion defines a cross-sectional shape that is rounder than a cross-sectional shape defined by said first and second lateral portions.

10. An annuloplasty device according to claim 1, further comprising:

means for identifying sets of suturing locations on said device, each said set corresponding to a discrete predetermined amount of cinching of an annulus of a heart valve.

11. An annuloplasty device according to claim 10, wherein:

said means for identifying includes visual indicia.

12. An annuloplasty device according to claim 11, wherein:

said visual indicia includes sets of visual indicia distinguished by at least one of color and shape.

13. An annuloplasty device according to claim 12, wherein:

said means for identifying includes discrete indicia corresponding to each of said sets of suturing locations, and said indicia corresponding to each of said sets are spaced apart from each other by a distance different than a distance by which indicia in the other of said sets is spaced apart.

14. An annuloplasty device according to claim 1, wherein:

said central portion has a length of approximately 20 to 25 mm.

15. An annuloplasty device, comprising:

a C-shaped structural component sized for a heart valve annuloplasty, said structural component including a central portion and first and second lateral portions,

wherein said structural component includes demarcations between said first lateral portion and said central portion and between said central portion and said second lateral portion facilitating removal of said central portion from between said first and second lateral portions.

16. An annuloplasty device according to claim 15, wherein:

said demarcations are structural.

17. An annuloplasty device according to claim 16, further comprising:

visual indicia coincident with said structural demarcations.

18. An annuloplasty device according to claim 17, wherein:

said structural component is provided with a relatively softer outer layer, and said visual indicia is provided on said outer layer.

19. An annuloplasty device according to claim 17, wherein:

said first and second lateral portions each include one of a trigone marking and a commissure marking.

20. An annuloplasty device according to claim 15, wherein:

said lateral portions are oriented substantially transverse to said central portion.

21. An annuloplasty device according to claim 15, wherein:

said central and first and second lateral portions define a plane, and said first and second lateral portions are relatively stiffer than said central portion in a direction transverse to said plane.

22. An annuloplasty device according to claim 15, wherein:

said structural component further includes an anterior portion anteriorly coupling said first and second lateral portions, such that said ring is annular in shape.

23. An annuloplasty device according to claim 15, wherein:

said central portion defines a cross-sectional shape that is rounder than a cross-sectional shape defined by said first and second lateral portions.

24. An annuloplasty device according to claim 15, further comprising:

means for identifying sets of suturing locations on said device, each said set corresponding to a discrete predetermined amount of cinching of an annulus of a mitral valve.

25. An annuloplasty device according to claim 24, wherein:

said means for identifying includes visual indicia.

26. An annuloplasty device according to claim 25, wherein:

said visual indicia includes sets of visual indicia distinguished by at least one of color and shape.

27. An annuloplasty device according to claim 24, wherein:

said means for identifying includes discrete indicia corresponding to each of said sets of suturing locations, and said indicia corresponding to each of said sets are spaced apart from each other by a distance different than a distance by which indicia in the other of said sets is spaced apart.

28. A method for heart valve annuloplasty, comprising:

a) providing an annuloplasty device having a central posterior portion and first and second lateral posterior portions;

b) coupling lateral posterior portions of an annulus of the heart valve to the first and second lateral posterior portions of the annuloplasty device; and

c) removing the central posterior portion of the annuloplasty device while maintaining the coupling between the lateral posterior portions of the annulus of the heart valve and the first and second lateral posterior portions of the annuloplasty device.

29. A method according to claim 28, wherein:

said providing includes providing an annuloplasty device in which said first and second lateral posterior portions are at least one of stiffer and thicker than said central posterior portion.

30. A method of restricting the annulus of a heart valve, the heart valve having an anterior portion and a posterior portion, the posterior portion defining lateral and central portions, comprising:

limiting expansion of the lateral portions of the posterior portion of the heart valve while leaving the central portion of the posterior portion of the of the heart valve unrestrained.

31. A method according to claim 30, wherein:

the heart valve is a mitral valve having A, P_1, P_2, and P_3 portions, and the lateral portions generally correspond to the P_1 and P_3 portions, and the central portion generally corresponds to the P_2 portion.

32. A method according to claim 31, wherein:

said limiting expansion includes coupling a first device adjacent P_1 and a second device adjacent P_2.

33. A method according to claim 31, wherein:

said limiting expansion includes cinching the lateral posterior portions relative to a device.

34. A method according to claim 31, wherein:

said limiting expansion includes cinching each of the lateral posterior portions relative to a discrete device.

35. An annuloplasty device for an annulus of a heart valve, comprising:

a structural component sized for the annulus of the heart valve, said structural component having a generally C-shaped portion including a central portion and first and second lateral portions; and

a relatively softer outer layer overlying said structural component, said outer layer including means for identifying sets of suturing locations through said outer layer, each said set corresponding to a discrete predetermined amount of cinching of the annulus.

36. An annuloplasty device according to claim 35, wherein:

said C-shaped portion is shaped for the posterior portion of a mitral valve.

37. An annuloplasty device according to claim 35, wherein:

said means for identifying includes visual indicia.

38. An annuloplasty device according to claim 37, wherein:

said visual indicia includes sets of visual indicia distinguished by at least one of color and shape.

39. An annuloplasty device according to claim 37, wherein:

said means for identifying includes discrete indicia corresponding to each of said sets of suturing locations, and said indicia corresponding to each of said sets are spaced apart from each other by a distance different than a distance by which indicia in the other of said sets is spaced apart.

40. An annuloplasty device according to claim 37, wherein:

said first and second lateral portions each include one of a trigone marking and a commissure marking adjacent an end opposite said central portion.

41. An annuloplasty device according to claim 37, wherein:

said structural component further includes an anterior portion anteriorly coupling said first and second lateral portions, such that said device is ring-shape.

42. An annuloplasty device according to claim 37, wherein:

said central and first and second lateral portions define a plane, and said first and second lateral portions are relatively stiffer than said central portion in a direction transverse to said plane.

43. An annuloplasty device for an annulus of a heart valve, comprising:

a structural component sized for placement about the annulus of the heart valve, said structural component having a generally C-shaped portion including a central portion and first and second lateral portions, said central portion having a different cross-sectional shape from said lateral portions.

44. An annuloplasty device according to claim 43, wherein:

said central portion has a rounder cross-sectional shape than said lateral portions.

45. An annuloplasty device according to claim 43, wherein:

said lateral portions are stiffer than said central portion.

46. An annuloplasty device according to claim 43, wherein:

said structural component is annular.

47. An annuloplasty device according to claim 43, wherein:

said C-shaped portion is located at a posterior portion of said structural component and defines a first curve, and said structural component includes an anterior portion which defines a second shallow curve.

48. An annuloplasty device for repair of a mitral valve after heart failure, comprising:

an annuloplasty ring having a posterior portion P with a central portion P2, and lateral portions P1 and P3, wherein said central portion P2 is provided with at most a single set of indicia corresponding to suture locations, and said lateral portions P1 and P3 each include multiple sets of discrete indicia corresponding to different suture locations, wherein said indicia corresponding to each of said sets of indicia on P1 and P3 are spaced apart from each other by a distance different than a distance by which indicia in the other of said sets of indicia on P1 and P3 is spaced apart.

49. An annuloplasty ring according to claim 48, wherein:

said ring is C-shaped.

50. An annuloplasty device for repair of a heart valve after heart failure, comprising:

an annuloplasty ring having, in one orientation, a posterior portion with a central portion, and lateral portions, and an anterior portion,

wherein said anterior portion is provided with at most a single set of indicia corresponding to suture locations, and said lateral portions each include multiple sets of discrete indicia corresponding to different suture locations, wherein said indicia corresponding to each of said sets of indicia on the lateral portions are spaced apart from each other by a distance different than a distance by which indicia in the other of said sets of indicia on the lateral portions is spaced apart.

51. An annuloplasty instrument system for implanting an annuloplasty ring, comprising:

a) a handle having first and second ends; and

b) an annuloplasty ring holder coupled to said first end,

said ring holder adapted to be coupled to an annuloplasty ring, and said ring holder including, in one orientation, anterior and posterior portions, said posterior portion including a central portion and relatively lateral portions, wherein said lateral portions of said holder each include multiple sets of discrete suture guides.

52. An annuloplasty instrument system according to claim 51, wherein:

said central portion of said holder includes at most a single set of discrete suture guides.

53. An annuloplasty instrument system according to claim 51, wherein:

said anterior portion of said holder includes at most a single set of discrete suture guides.

54. An annuloplasty instrument system according to claim 51, further comprising:

c) an annuloplasty ring removably coupled to said implant holder of said instrument.

55. A method of restricting the annulus of a heart valve, the heart valve having an leaflets defining junctions, comprising:

selectively cinching the junctions such that the annulus of the valve is reduced at the locations only adjoining the junctions and not at other locations around the annulus of the valve.

56. A method according to claim 55, wherein:

said cinching is performed by shape change of at least one SMA device upon subjecting the at least one SMA device to a predetermined amount of heat energy.

57. A method according to claim 56, wherein:

said at least one SMA device has a length of not more than approximately 20 mm.

58. A method according to claim 56, wherein:

said at least one SMA device has a length of not more than approximately 15 mm.

59. A method according to claim 56, wherein:

said at least one SMA device has a fabric or plastic layer over a portion thereof.

60. A method according to claim 56, further comprising:

implanting an implant which stabilizes, but which does not cinch a portion of the annulus along a leaflet.

61. A steerable surgical catheter device for use in reducing a leak of a heart valve, comprising:

a) an elongate tubular element having a distal end;

b) an SMA implant having a length not exceeding approximately 40 mm coupled to or within the distal end of the tubular element;

c) a steering mechanism for steering the distal end of the tubular element;

d) a system for applying heat energy to the SMA implant to cause the SMA implant to change shape configuration; and

e) a mechanism for releasing the implant from the tubular element.

62. A steerable surgical catheter device according to claim 61, wherein:

said SMA implant has a length not exceeding approximately 15 mm.

63. An annuloplasty device, comprising:

an implant of shape memory alloy of not more than approximately 20 mm in length and having a pre-activated configuration and, when subject to a predetermined amount of heat energy, a post-activated configuration, wherein said pre-activated and post-activated configurations are one of the following:

a) pre-activated shape of straight or arced and post-activated shape of a 'U';

b) pre-activated shape of straight or arced and post-activated shape of a 'C' with curled ends;

c) pre-activated shape generally of a 'C' and a post-activated shape of a 'C' with curled ends;

d) pre-activated shape of a 'C' and post-activated shape of a spiral; and

e) pre-activated shape of straight or arced and post-activated shape of a 'V' with curled ends.

64. An implant according to claim 63, wherein:

said implant has a length not exceeding approximately 15 mm.

65. An annuloplasty device for the mitral valve, the mitral valve having anterior and posterior leaflets, comprising:

first and second lateral portions and a central portion, said lateral portion comprising shape memory alloy having a pre-activated configuration and, when subject to a predetermined amount of heat energy, a post-activated configuration,

the central portion not being modified in shape when subject to said predetermined amount of heat energy,

wherein when the implant is implanted about the posterior leaflet and said predetermined heat energy is applied, said implant is adapted to cinch respective portions of the lateral posterior leaflet of the mitral valve but not the central portion of the leaflet.

66. An annuloplasty device according to claim 65, wherein:

said central portion of said device is sufficiently stiff so as to stabilize the central portion of the leaflet.

67. A method of performing heart valve annuloplasty, the heart valve having an leaflets defining junctions about an annulus, the method comprising:

inserting an implant made of shape memory alloy through or about a junction of the annulus; and

subjecting the implant to a predetermined amount of heat energy so as to cause the implant to change shape, wherein such shape change causes localized reconfiguration of the annulus at the junction.

68. A method according to claim 67, wherein:

said implant is not implanted at non-junction locations around the annulus of the valve.

69. A method according to claim 68, wherein:

said implant is implanted internally within the heart.

70. A method according to claim 68, wherein:

said implant is coupled to the heart externally of the heart.

71. A method according to claim 70, wherein:

said implant is implanted through the coronary sinus.

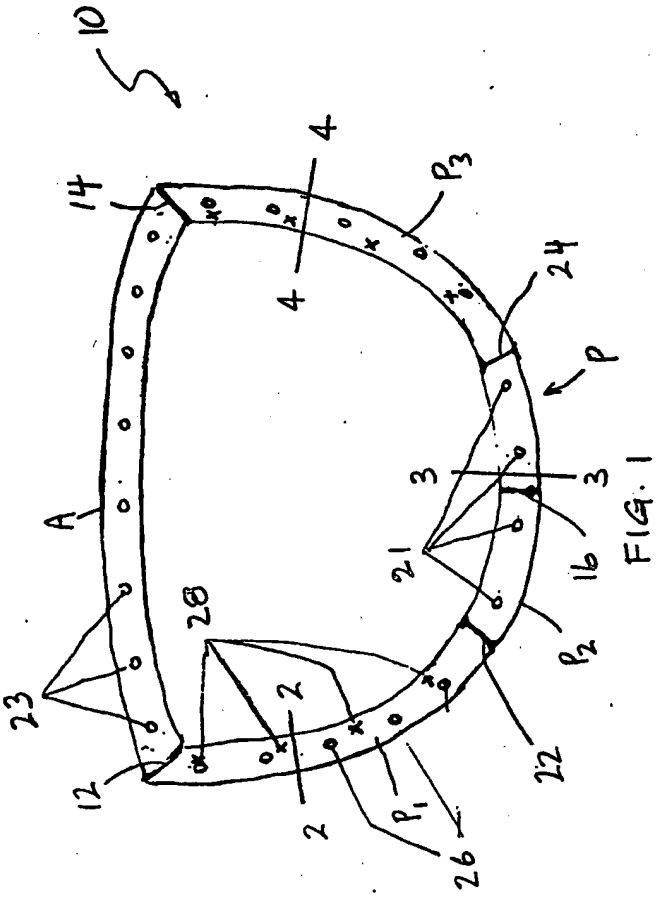

FIG. 1

FIG. 4

FIG. 3

FIG. 2

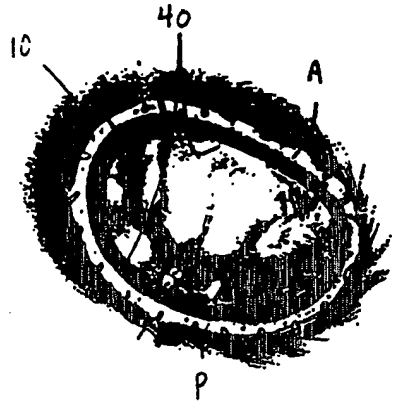

FIG. 5

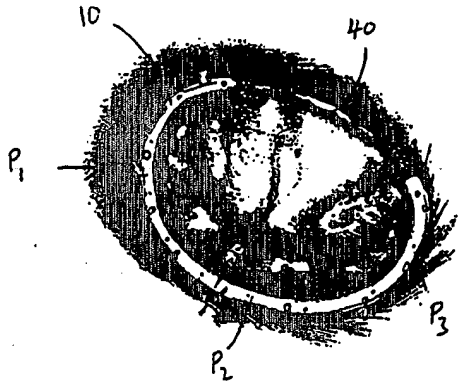

FIG. 6

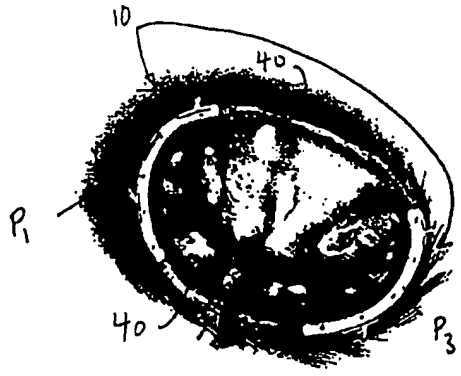

FIG. 7

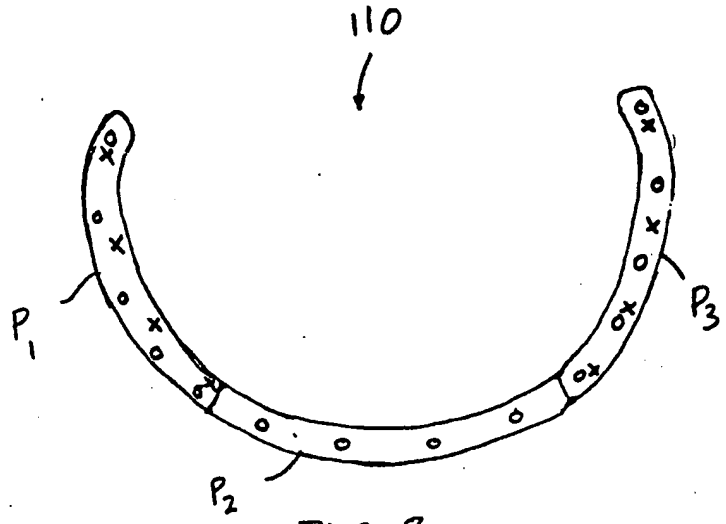

FIG. 8

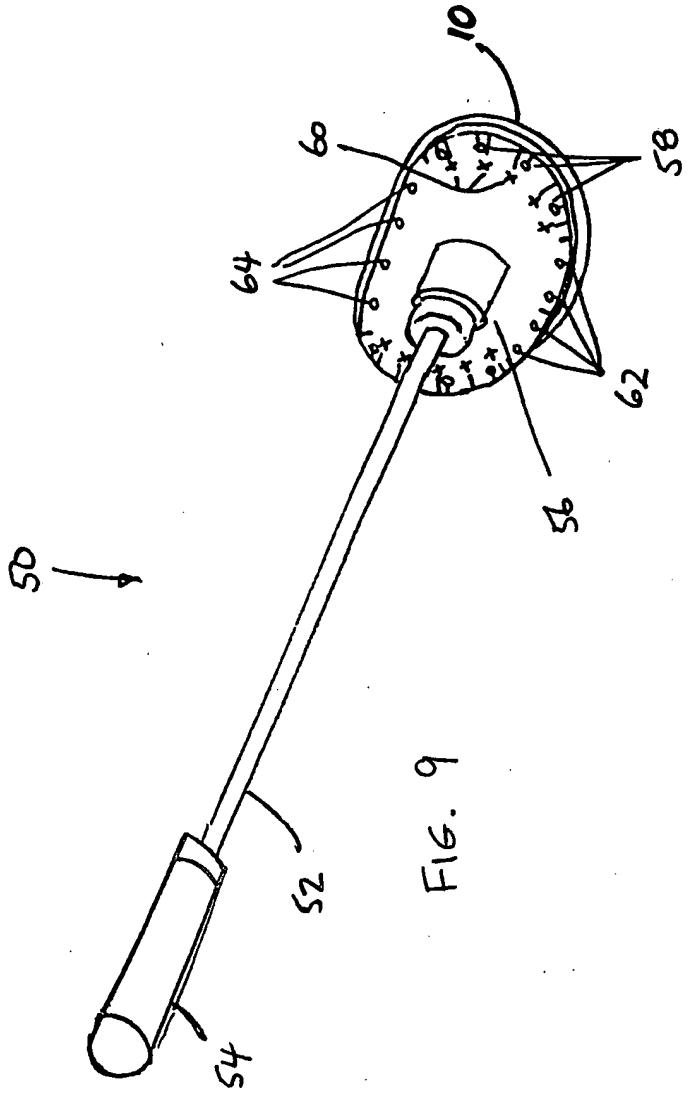

FIG. 9

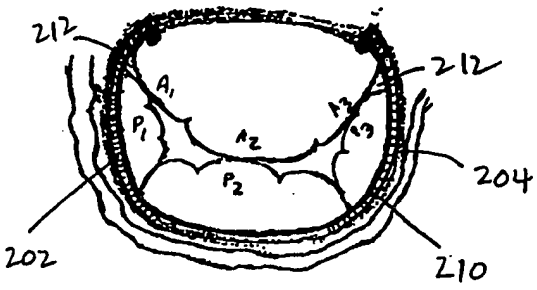

FIG. 10

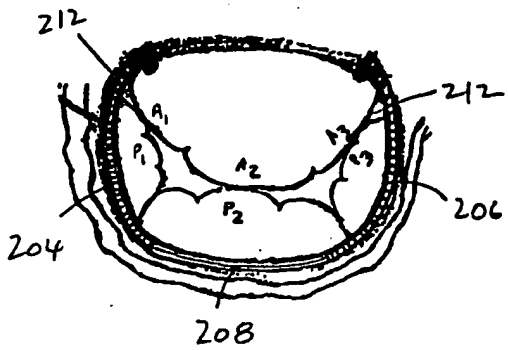

FIG. 11

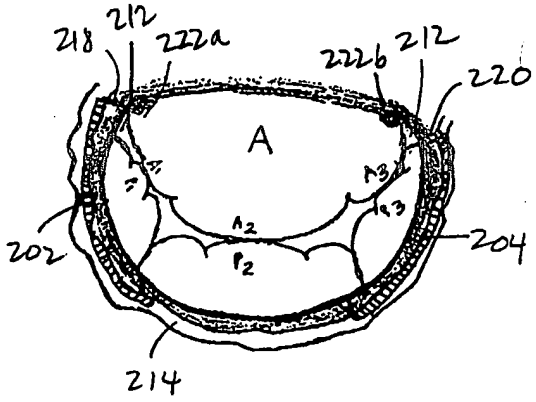

FIG. 12

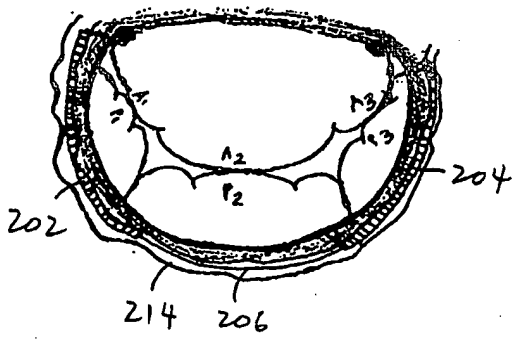

FIG. 13

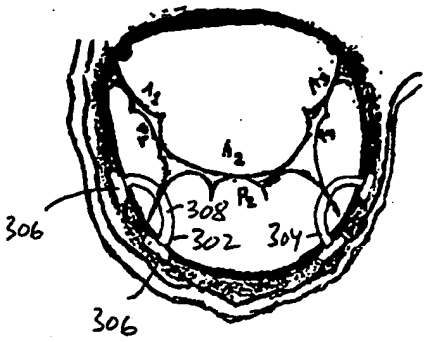

FIG. 14

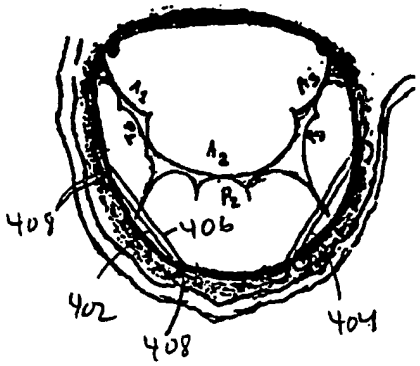

FIG. 15

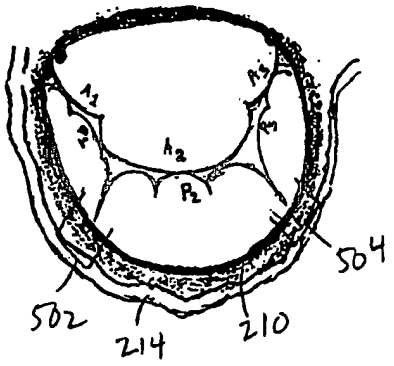

FIG. 16

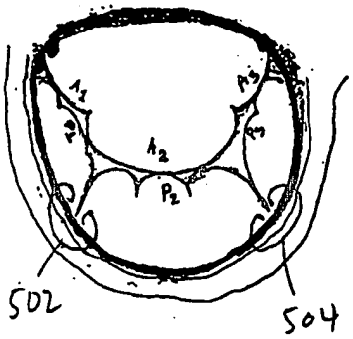

FIG. 17

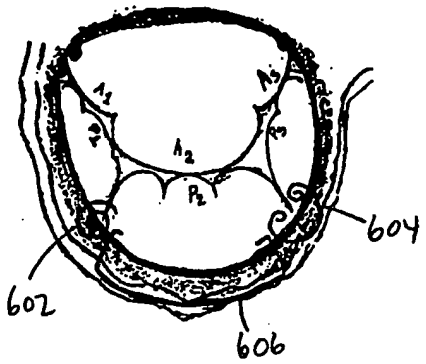

FIG. 18

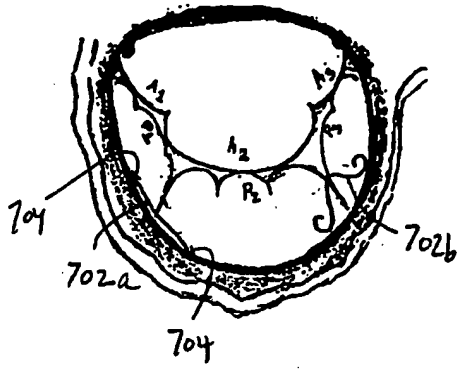

FIG. 19

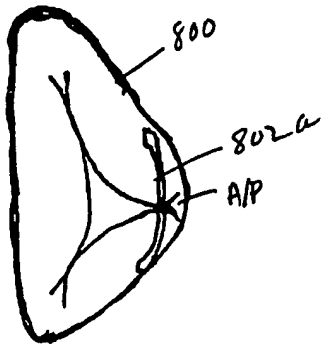

FIG. 20

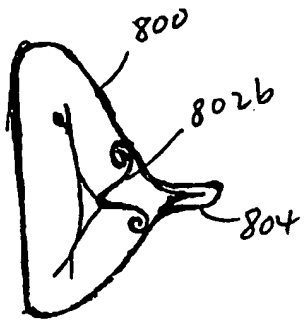

FIG. 21

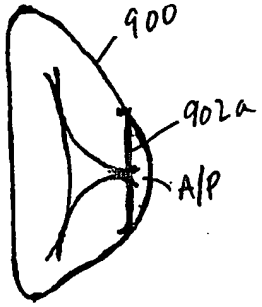

FIG. 22

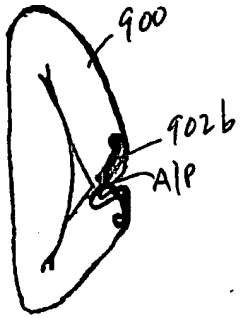

FIG. 23

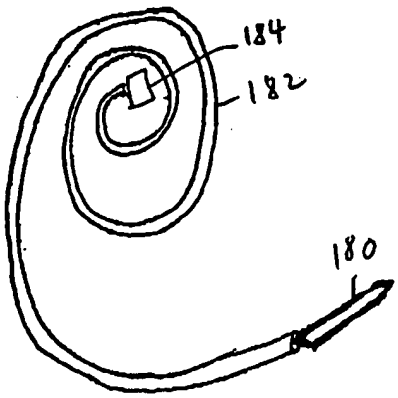

FIG. 24

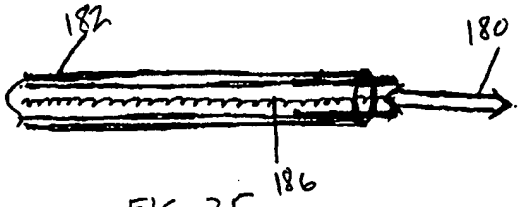

FIG. 25

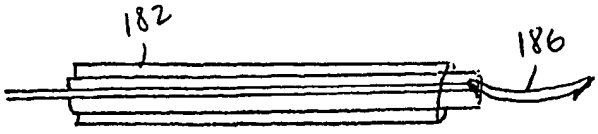

FIG. 26

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/21886

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61F 2/24
US CL : 623/2.36
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 623/2.36, 2.37, 2.38, 2.39, 2.4, 2.41, 900

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,174,332 B1 (LOCH et al) 16 January 2001 (16.01.2001), see figures 1-3b and entire specification	1-12, 15-26, 30-31, 33-34, 35-38, 40-41, 43-47
X	US 6,074,419 A (HEALY et al) 13 June 2000 (13.06.2000), see figure 7 and entire specification	1-8, 10-22, 24-29, 35-42, 48-50
X	US 5,011,481 A (MYERS et al) 30 April 1991 (30.04.1991), see entire specification	51-54
X	US 2003/0120340 A1 (LISKA et al) 26 June 2003 (26.06.2003), see entire specification	30-34, 55-71

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search
31 August 2004 (31.08.2004)

Date of mailing of the international search report
02 NOV 2004

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Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/21886

Continuation of B. FIELDS SEARCHED Item 3:
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search terms: shape memory, heat, energy, nitinol, indicia, marking, marker, cut, annuloplasty, aperture